UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Bobby Tate Bowman,

Plaintiff,

v.

Civil No. 10-1946 (JNE/SER)
ORDER

Wyeth, LLC, f/k/a Wyeth, Inc.,
Wyeth Pharmaceuticals, Inc., and
Teva Pharmaceuticals USA, Inc.,

Defendants.

Plaintiff Bobby Tate Bowman ("Bowman") brought this action against Defendants Wyeth, LLC, Wyeth Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc. related to injuries he suffered from ingesting the prescription drug Reglan/metoclopramide. Now before the Court is Defendant Teva Pharmaceuticals USA, Inc.'s ("Teva") Motion for Judgment on the Pleadings.

I. BACKGROUND

Bowman filed this action on May 3, 2010, alleging claims of negligence and negligent misrepresentation and fraud. His claims are based on allegations that he was prescribed and ingested the prescription drug Reglan—and/or its generic equivalent, metoclopramide—and that his long-term use of the drug caused him to develop a condition known as Tardive Dyskinesia.[1] Teva manufactures and sells metoclopramide. Bowman alleges that Teva knew that the labeling for metoclopramide was inadequate and contained false and misleading information regarding metoclopramide's side effects. He further alleges that Teva encouraged long-term use of

[1] Tardive Dyskinesia is a severe and often permanent disfiguring neurological movement disorder.

metoclopramide and concealed critical information indicating that long-term use of metoclopramide was unsafe.

On February 24, 2011, the Court stayed proceedings pending the United States Supreme Court's decision in the consolidated cases of *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010) and *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009). On June 23, 2011, the Supreme Court decided *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), holding that state-law tort claims based on an alleged failure to warn of the risks of generic medications are preempted by federal law because it is impossible to comply with both a state law duty to strengthen a generic drug warning and the federal mandate that a generic drug's labeling be the same as that of the brand-name drug. On August 23, 2011, the Court lifted the stay in this action. Teva has moved for Judgment on the Pleadings, arguing that all of Bowman's claims are preempted under *PLIVA, Inc. v. Mensing*.

II. DISCUSSION

A court should grant judgment on the pleadings only if the moving party clearly establishes that there are no material issues of fact and that it is entitled to judgment as a matter of law. *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir.1999). A court evaluates a motion for judgment on the pleadings brought under Rule 12(c) of the Federal Rules of Civil Procedure under the same standard as a motion brought under Rule 12(b)(6). *See Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir.1990). In deciding a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a court must accept the facts alleged in the complaint as true and grant all reasonable inferences in favor of the plaintiff. *Crooks v. Lynch*, 557 F.3d 846, 848 (8th Cir.2009). Although a complaint is not required to contain detailed factual allegations, "[a] pleading that offers 'labels and

conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* A court may consider the complaint, matters of public record, orders, materials embraced by the complaint, and exhibits attached to the complaint in deciding a motion to dismiss under Rule 12(b)(6). *Porous Media*, 186 F.3d at 1079.

A. The *Mensing* Decision

Mensing involved a plaintiff who ingested Reglan/metoclopramide and asserted a number of Minnesota tort-law claims against the brand-name and generic manufacturers of the drug. Her complaint asserted product liability claims of failure-to-warn, design defect, and manufacturing defect, as well as claims of negligence, negligent misrepresentation, misrepresentation by omission, constructive fraud, fraud by concealment, breach of express and implied warranties, and violations of several Minnesota consumer protection statutes. The generic manufacturer defendants moved to dismiss the complaint, asserting that the plaintiff's claims were essentially failure-to-warn claims and were preempted by the federal Food, Drug & Cosmetic Act. The plaintiff opposed the motion, and argued that even if her failure-to-warn claims were preempted, her other tort claims—such as design defect, negligent testing, and misrepresentation and fraud—would not be preempted. The district court granted the defendants' motion, noting that "[a]lthough Plaintiff has asserted a variety of claims against Actavis and Pliva, at the core of all of Plaintiff's claims is the basic assertion that Actavis and Pliva failed to adequately warn about

the association between long-term ingestion of [metoclopramide] and movement disorders." *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056, 1058 (D. Minn. 2008); *see also id.* at 1061 n.6 (stating that "all of Plaintiff's claims are essentially 'failure to warn' claims and are encompassed by the Court's preemption analysis"). The court found that because, under federal law, a generic drug manufacturer cannot unilaterally strengthen or change a drug label, any state law imposing such a duty is preempted. *Id.* at 1064-65. The court rejected the plaintiff's argument that the generic manufacturers could have satisfied their duty by providing information to the Food and Drug Administration ("FDA") and having the FDA determine whether the labeling should be revised. "The outcome of any such request to make a revision is uncertain and would require speculation as to what the FDA might have done." *Id.* at 1065. Finally, the court rejected the plaintiff's argument that the defendants could have employed other means, such as submitting "Dear Doctor" letters, to warn health care professionals of the risks of metoclopramide, finding that such a duty would directly conflict with the statutory scheme of the Hatch-Waxman Act. *Id.*

On appeal, the Eighth Circuit reversed the district court's decision, finding that it would not be impossible for generic manufacturers to comply with both a heightened state law duty to warn and federal law. *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009). The court stated that regardless of whether the generic manufacturers could unilaterally enhance a label warning, they "could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved." *Id.* at 608. The generic manufacturers also "could have suggested that the FDA send out a warning letter to health care professionals." *Id.* at 610. The court noted that there was no evidence suggesting that the FDA would have rejected such a label change proposal, and cited *Wyeth v. Levine*, 555 U.S. 555, 571 (2009), for the proposition that "absent clear evidence that the FDA would not have approved a

change to [the drug]'s label, we will not conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements." *Mensing*, 588 F.3d at 610. The court stated,

> [t]he generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales. If [plaintiff]'s injuries resulted from their failure to take steps to warn their customers sufficiently of the risks from taking their drugs, they may be held liable.

Id. at 611.

The United States Supreme Court granted certiorari and on June 23, 2011, decided *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). The Court reversed the Eighth Circuit's decision and found that it is impossible for a generic manufacturer to comply with both a heightened state law duty to warn and FDA regulations that require a generic manufacturer to have the same labels as the brand name drug.[2] *Id.* at 2577-78. The Court first noted that if the manufacturer knew or should have known of a high risk of tardive dyskinesia related to the long-term use of the drug, and that its label did not adequately warn of that risk, "state law required the Manufacturers to use a different, safer label." *Id.* at 2574. Federal law, however, requires that the warning label for a generic drug be the same as the label for the brand name drug. *Id.* (citing § 355(j)(2)(A)(v); § 355(j)(4)(G); 21 C.F.R. §§ 314.94 (a)(8), 314.127(a)(7)). Thus, while brand-name manufacturers are responsible for the accuracy and adequacy of its label, "generic drug manufacturers have an ongoing federal duty of 'sameness.'" *Id.* at 2574-75.

Deferring to the FDA's interpretation of its regulations, the Court rejected the plaintiffs' arguments that the FDA's "changes-being-effected" process allowed generic manufacturers to unilaterally change their labels or that generic manufacturers could provide additional warnings

[2] The Supreme Court in *Mensing* also reversed the Fifth Circuit's decision in *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010).

through "Dear Doctor" letters. *Id.* at 2575-76 ("A Dear Doctor letter that contained substantial new warning information would not be consistent with the drug's approved labeling. Moreover, if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'").

Noting that under the Supremacy Clause, state law must give way to federal law where the laws directly conflict, the Court found that it was impossible for the generic drug manufacturers to comply with both state and federal law. *Id.* at 2577.

> If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. Taking [plaintiffs'] allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.

Id. at 2578. Even if there is a federal duty to ask the FDA for assistance in changing a drug label, the Court found that such a duty would not change the analysis. *Id.* ("Although requesting FDA assistance would have satisfied the Manufacturers' federal duty, it would not have satisfied their state tort-law duty to provide adequate labeling. State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label."). The Court also rejected the plaintiffs' argument that the manufacturers *could* have asked the FDA for assistance, which *might* have resulted in a labeling change for the drug. *Id.*

> The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it. Accepting [plaintiffs'] argument would render conflict preemption largely meaningless because it would make most conflicts between state and federal law illusory. We can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it. . . .

> If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force. We do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless." *Id.*

Id. at 2579 (citation omitted). "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 2581. "Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action. The only action the Manufacturers could independently take—asking for the FDA's help—is not a matter of state-law concern. [Plaintiffs'] tort claims are pre-empted." *Id.*

Finally, noting the dissimilar statutory schemes for brand-name and generic drugs, the Court recognized that had the plaintiffs taken the brand-name drug, Reglan, rather than the generic drug, metoclopramide, "their lawsuits would not be preempted." *Id.* "We acknowledge the unfortunate hand that federal drug regulation has dealt [plaintiffs] and others similarly situated." *Id.*[3] The Court reversed the judgments of the Fifth and Eighth Circuits and remanded the cases for further proceedings consistent with the opinion.

The plaintiffs petitioned the Court for a rehearing, asserting that the Court "overlook[ed] the fact that the Petitioner generic drug companies could have 'independently' complied with both state and federal law simply by suspending sales of generic metoclopramide with warnings that they knew or should have known were inadequate." Resp'ts' Pet. for Reh'g 1. The Supreme Court denied the petition. *PLIVA, Inc. v. Mensing*, 132 S. Ct. 55 (2011).

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[3] The dissent also noted that "[a]s a result of today's decision, whether a consumer harmed by inadequate warnings can obtain relief turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug." *Id.* at 2583.

The plaintiff in *Mensing* then asked the Eighth Circuit to allow supplemental briefing regarding the implications of the Supreme Court's ruling. While acknowledging that she could no longer pursue her failure-to-warn claims, she argued that claims based on other theories of liability survived the Court's decision. First, she contended that claims arising from the generic manufacturers' failure to communicate the FDA-approved changes to the Reglan label in July 2004 were not preempted. The generic manufacturers, she argued, could have implemented the labeling change "independently" once the Reglan labeling change was approved, and so claims based on this failure of the generic manufacturers were not preempted. Second, she asserted that the manufacturers should have suspended sales of the drug until an adequate label was approved by the FDA. "Nothing in federal law prohibited the Generic Drug Company Appellees from suspending sales of their drug, and action the companies could have taken entirely on their own initiative." Appellant's Mot. for Leave to File Supplemental Brief 4. Thus, she argued, claims based on failure to suspend sales were not preempted. Finally, she argued that the Supreme Court only addressed federal preemption of failure-to-warn claims, and so non-failure-to-warn claims, such as her claims of negligence, breach of express warranty, fraud, misrepresentation, and violations of various Minnesota consumer protection statutes, would not be preempted. The Eighth Circuit rejected the plaintiff's arguments and denied her motion. The court vacated the portions of its prior opinion that found the failure-to-warn claims against the generic manufacturers were not preempted. It then ordered that the judgment of the district court be affirmed. *Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011).

Similarly, in the *Demahy* case, the Fifth Circuit vacated the district court's order and remanded the case for entry of judgment in favor of the generic manufacturer. *Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011). Pursuant to the Fifth Circuit's mandate, the district

court entered judgment in favor of the defendants and dismissed the case with prejudice. *Demahy v. Wyeth, Inc.*, Civil No. 08-3616, 2011 WL 5505399 (E.D. La. Aug. 30, 2011). The plaintiff in *Demahy* had also asserted claims of products liability, failure-to-warn, design defect, negligence, misrepresentation, and fraud.

B. Application of *Mensing* to the Complaint

Like the plaintiff in *Mensing*, Bowman urges the Court to adopt a very narrow reading of the Supreme Court's decision. He asserts that the only claims that are preempted are failure-to-warn claims relating to a generic manufacturer's failure to unilaterally change its labeling to differ from the approved labeling for the brand-name drug. He argues that *Mensing* did not consider whether a generic manufacturer could be "liable for *selling* an unreasonably dangerous product, for accompanying its product with *false information* about potential risks associated with metoclopramide, and for *concealing* important safety information from the FDA, consumers, and the medical community." Pl.'s Resp. Mem. 5 (emphasis in original). Thus, Bowman contends that he has asserted non-failure-to-warn claims that are not preempted. He also believes that claims based on Teva's alleged failure to include or communicate the 2004 labeling changes to the brand-name drug are not preempted.

1. Bowman's "Other" Theories of Liability

Bowman contends that *Mensing* only pertained to failure-to-warn claims and does not affect claims based on other theories of liability. He states that in addition to providing inadequate warnings, Teva also "provided false information about the drug, concealed important safety information, and knowingly placed an unreasonably dangerous product into the stream of commerce . . . ." Pl.'s Resp. Mem. 2. Although Bowman attempts to distinguish his various theories of liability, his claims are all based on Teva's alleged failure to provide adequate

information or warnings, and thus are preempted under *Mensing*. In fact, his Complaint belies his own argument: "This case involves Pharmaceutical Defendants' *failure to warn* doctors and patients of information within their knowledge or possession which indicated that the subject Reglan/metoclopramide, when taken for long periods of time, caused serious, permanent, and debilitating side effects, including tardive dyskinesia." Complaint ¶ 27 (emphasis added). Like *Mensing*, "at the core of all of Plaintiff's claims is the basic assertion that [Teva] failed to adequately warn about the association between long-term ingestion of [metoclopramide] and movement disorders." *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d at 1058; *see also Moretti v. Mut. Pharm. Co.*, Civil No. 10-896, 2012 WL 465867, at *4 (D. Minn. Feb. 13, 2012) ("Despite the different 'labels' given these claims, the essence of these claims is that important safety information as to metoclopramide was not disseminated, or made clear, to the public or the medical community. In other words, Defendants failed to warn of material safety information concerning metoclopramide.").

Moreover, Bowman can point to no differences between his claims and those dismissed in *Mensing*. Even if the Supreme Court did not expressly hold that all state-law claims, even those not specifically labeled as "failure-to-warn" claims, are preempted, the Eighth Circuit appears to have adopted this position when it affirmed the district court's dismissal of *all* of Mensing's claims. Like Bowman, Mensing had also asserted claims of negligence, misrepresentation, and fraud. Mensing had also argued, to both the Supreme Court and the Eighth Circuit, that the generic drug manufacturers could have complied with state and federal law by suspending sales of the generic drug, or by withdrawing the drug from the market until the labeling could be made adequate. Both courts rejected this argument. There are no claims in Bowman's Complaint that were not also asserted in *Mensing*, and the Court cannot find any

meaningful distinction between these two cases.[4] *See Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5h Cir. 2011) (dismissing as preempted claims of failure-to-warn, design defect, negligence, misrepresentation, and fraud); *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011) (finding claims of products liability, negligence, negligence per se, fraud, fraud by concealment, and breach of express and implied warranties preempted under *Mensing*); *Gaeta v. Perrigo Pharm. Co.*, No. 09-15001, 2012 WL 605678 (9th Cir. Feb. 27, 2012) (affirming the district court's dismissal of plaintiff's design defect, marketing defect, breach of express and implied warrant, negligence, and deceit by concealment claims, based on the *Mensing* decision). Thus, Bowman's negligence and negligent misrepresentation and fraud claims are preempted.

2. 2004 Labeling Change to Reglan

Bowman argued in his briefs that Teva could still be held liable, even after *Mensing*, for failing to update its labeling after the FDA approved a labeling change to the brand-name drug, Reglan, in July 2004.[5] The Court need not address whether this type of claim is preempted under *Mensing* because Bowman does not assert this claim in his Complaint. His Complaint contains no specific allegation that he ingested metoclopramide after July 2004 (in fact, he does not even allege that he ingested metoclopramide for more than twelve weeks), nor does it contain any factual allegations relating to the 2004 labeling change whatsoever. Bowman conceded at oral argument that he asserts no arguments regarding the purported lag between Reglan's approved labeling change in July 2004 and the generic drug manufacturer's inclusion of that update in its

[4] Despite Bowman's arguments that claims of design defect and breach of express and implied warranties survive the Supreme Court's decision in *Mensing*, the *Mensing* complaint itself contained these types of claims and was nevertheless dismissed. Further, Bowman's Complaint does not expressly allege such claims, as conceded during oral argument, nor are there any factual allegations to support claims of that nature.

[5] In July 2004, the FDA approved the addition of "therapy should not exceed 12 weeks in duration" to the Reglan label.

own labeling. Further, Bowman continues to contend that even the post-July 2004 Reglan warnings were inadequate—and there is no duty for a manufacturer to provide an *inadequate* warning. Because Bowman makes no claim regarding Teva's alleged failure to update its labeling after the 2004 labeling change for Reglan was approved, his argument is without merit.[6]

III. CONCLUSION

The Supreme Court in *PLIVA, Inc. v. Mensing* held that state-law tort claims based on a generic drug manufacturer's failure to warn are preempted by federal law. The sweeping language of the Supreme Court's opinion, as well as the Eight Circuit's affirmation of the dismissal of all of Mensing's claims—even those claims not labeled as "failure-to-warn" claims—lead this Court to find that all of Bowman's claims are preempted under the theory of conflict preemption. This Court's conclusion is in accordance with the tsunami of cases that have been decided since the *Mensing* decision. Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

1. Teva's Motion for Judgment on the Pleadings [Docket No. 43] is GRANTED.

2. Bowman's Complaint against Teva is DISMISSED WITH PREJUDICE.

Dated: March 2, 2012

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge

[6] Moreover, it appears as though the Eighth Circuit *has* addressed this claim and found it, too, to be preempted under *Mensing.* Mensing, who ingested metoclopramide through 2005, brought this issue to the Eighth Circuit's attention when she requested permission to file supplemental briefing—the court denied that request.